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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,533	10/068,533 02/05/2002		Robert H. Dahla	CB-11-1	9992
21394	7590	590 10/13/2005	•	EXAMINER	
		ORPORATION	PEFFLEY, MICHAEL F		
680 VAQUE SUNNYVA				ART UNIT	PAPER NUMBER
	,			3739	

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	10/068,533	DAHLA ET AL.					
Office Action Summary	Examiner	Art Unit					
	Michael Peffley	3739					
The MAILING DATE of this communication app Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 27 Ju	<u>ıly 2005</u> .						
2a) This action is FINAL . 2b) ⊠ This action is non-final.							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.					
Disposition of Claims							
4) Claim(s) 1-50 is/are pending in the application.							
4a) Of the above claim(s) <u>1-11,13-21 and 27-50</u> is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>12 and 22-26</u> is/are rejected.	6)⊠ Claim(s) <u>12 and 22-26</u> is/are rejected.						
	7) Claim(s) is/are objected to.						
8) ☐ Claim(s) are subject to restriction and/o	r election requirement.						
Application Papers							
9)☐ The specification is objected to by the Examine	r.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correct	, , , , , ,	•					
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.					
Priority under 35 U.S.C. § 119		,					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
See the attached detailed Office action for a list	of the certified copies not receive	···					
Attachment(s)							
1) Notice of References Cited (PTO-892)	4) Interview Summary						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date. 5) Notice of Informal Patent Application (PTO-152)							
Paper No(s)/Mail Date 🔀 🖟 🖒	6) Other:	aton Application (FTO-192)					
J.S. Patent and Trademark Office PTOL-326 (Rev. 7-05) Office Ac	etion Summary Pa	rt of Paper No./Mail Date 10042005					

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Election/Restrictions

Applicant's election without traverse of the invention of Group III (Claims 12-33) and the embodiment of Figure 16B in the reply filed on July 27, 2005 is acknowledged.

It appears that applicant has indicated that all claims 12-33 of the elected invention also read on the elected embodiment. The examiner disagrees. The examiner asserts that claims 12 and 22-26 read on the elected embodiment of Figure 16B. Claims 13-17 and 27-33 recite an electrode embodiment as shown if Figure 19A, and claims 18-21 recite features from the embodiment shown in Figure 17B. As such, claims 1-11, 13-21 and 27-50 are withdrawn from further consideration.

Priority

It is noted that in addition to the applications recited in the Cross Reference to Related Applications section of the specification there are numerous other co-pending applications which disclose and claim very similar and/or identical subject matter. In accordance with 37 CFR 1.105 and MPEP 704.11(a) subsection G, applicant is respectfully requested to disclose all co-pending applications and related patents and identify the specific claims of those applications and/or patents which may present double patenting issues with the instant application claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Nardella (5,334,193).

As shown in Figures 1 and 2, Nardella discloses a device comprising an electrosurgical probe (14) having active and return electrodes (18,20). The return electrode and the active electrode are each coil electrodes with about 10 turns and are adapted to ablate and/or coagulate tissue. The method of using the device inherently includes placing the device in proximity to tissue and applying a high frequency voltage between the active and return electrodes to ablate tissue. Nardella specifically teaches of the known voltage (col. 5, lines 60-65) and temperature ranges (col. 4, lines 65-66) used to treat tissue, which ranges are within the range set forth in applicant's claims. The probe includes a shaft including two lumens through which the leads (24,26) extend creating the active and return electrodes.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Abele et al (5,403,311).

Figure 8 of the Abele et al reference discloses a device comprising an elongate probe having active (56) and return (58,60) electrodes at the distal end. The return electrode(s) include a coil having about 3-10 turns. Column 9, lines 9-25 discloses how the helical electrodes are connected to ground so the device acts in a bipolar manner

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with active electrode (56). The method of using the device inherently includes providing the device in proximity to tissue and delivering energy from the active to the return electrode to ablate tissue.

Claims 12 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (5,507,743).

Edwards et al disclose an ablation device comprising an elongate probe (22 – Figure 4a) having active and return electrodes (12,14) at the distal end. Column 5, lines 15-16 disclose the return electrode as having 4 or fewer coils, and column 1, lines 58-60 disclose that temperatures of greater than 45 degrees Celcius are used to treat tissue. The step of providing the electrodes to tissue and delivering energy from the active to the return electrode is fully supported in the Edwards et al disclosure.

Claims 12 and 22-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Ciarrocca et al (6,837,888)

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

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It is noted that the Ciarrocca et al ('888) patent claims the benefit of US

Provisional Application No. 60/326,664 with a filing date of October 2, 2001. The instant application claims the benefit of earlier filed applications. However, none of the earlier filed applications provide support for the coiled return electrode as set forth in the instantly examined claims and applicant is therefore not accorded the benefit of the earlier filing dates of those related applications.

Figure 57(b) of the Ciarrocca et al patent discloses an embodiment substantially identical to applicant's claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nardella (193) in view of the teaching of Imran et al (5,348,554).

The Nardella device has been previously addressed. Nardella fails to specifically disclose a probe body made from an extruded polyurethane.

The examiner maintains that the use of any well known medical grade material to make a catheter or probe device would be an obvious design consideration for one of ordinary skill in the art. In support of this assertion, the examiner relies on Imran et al who specifically disclose a probe device very much analogous to the Nardella probe. In

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particular, Imran et al disclose that the probe is made from a polyurethane extrusion (col. 2, line 64 through col. 3, line 2).

To have fabricated the Nardella device from any well known flexible polymer, including an extruded polyurethane, would have been an obvious design consideration for one of ordinary skill in the art, particularly since Imran et al teach that it is known to make analogous probes from such a material.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele et al ('311) in view of the teaching of Nardella ('193).

Abele et al fail to disclose the specific power levels and temperature ranges used during the cardiac ablation procedure.

As addressed previously, Nardella disclose another cardiac ablation device and specifically teach of the known voltage and temperature ranges associated with such devices.

To have operated the Abele et al device in any well known parameter range for the ablation of cardiac tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Nardella.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele et al ('311) in view of the teaching of Stevens-Wright et al (5,715,817).

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Abele et al fail to specifically disclose the use of multiple lumens for providing the active and return electrodes to the distal end of the device. Abele et al is simply silent with respect to the cross-section components of the catheter.

Stevens-Wright et al disclose an electrosurgical device, and specifically teach that electrode leads may be provided through individual channels (see Figures 9-13) and connected to electrodes.

To have provided the Abele et al device with multiple lumens for supporting the multiple electrodes/leads provided at the distal end of the device would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Stevens-Wright et al.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abele et al ('311) in view of the teaching of Imran et al ('554).

Abele et al fail to specifically disclose making the catheter probe from a polyurethane extrusion. Again, the examiner maintains that the use of any well-known materials for making probes would be an obvious design consideration.

Imran et al, as addressed previously, disclose a probe device very much analogous to the Abele et al probe. In particular, Imran et al disclose that the probe is made from a polyurethane extrusion (col. 2, line 64 through col. 3, line 2).

To have fabricated the Abele et al device from any well known flexible polymer, including an extruded polyurethane, would have been an obvious design consideration

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for one of ordinary skill in the art, particularly since Imran et al teach that it is known to make analogous probes from such a material.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 22-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-124 of U.S. Patent No. 6,837,888. Although the conflicting claims are not identical, they are not patentably distinct from each other because providing the electrodes as movable electrodes to afford more flexibility in treating tissue is deemed an obvious design consideration for one of ordinary skill in the art.

Claims 12 and 22-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 10/072,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a spacer

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to maintain electrical separation of the active and return electrodes is deemed an obvious design consideration for one of ordinary skill in the art.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley

Primary Examine

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mp October 4, 2005